

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Patent of) Group Art Unit: 1638
Yong-Li Ruan et al.) Examiner: RUSSELL KALLIS
U.S. Patent No. 7,498,492) Confirmation No.: 5391
Application No.: 10/003,405)
Filed: December 6, 2001)
For: MODIFICATION OF SUCROSE)
SYNTHASE GENE EXPRESSION IN)
PLANT TISSUE AND USES)
THEREFOR)

**REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT
PURSUANT TO 37 C.F.R. 1.705(d)**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Patentees hereby request reconsideration the patent term adjustment indicated in the subject patent. A revision to the patent term adjustment that was indicated in the Notice of Allowance appears in the patent. Therefore, pursuant to 37 C.F.R. § 1.705(d), this request is timely filed within two months of the date the patent issued.

Patentees respectfully submit that the revised patent term adjustment was incorrectly calculated in that the Office has failed to take the decision in *Wyeth v. Dudas*, 88 U.S.P.Q.2d 1538 (D.D.C. 2008) into consideration in calculating the revised patent term adjustment. In particular, the Office appears to have calculated the revised patent term adjustment on the basis that the period of delay under 35 U.S.C. § 154(b)(1)(B) and 37 C.F.R. § 1.702(b) is overlapping with every period of delay for which adjustment must be afforded under 35 U.S.C. § 154(b)(1)(A) and 37 C.F.R. § 1.702(a).

It is understood that the position of the Office in this regard has previously been as follows:

[T]he Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35

U.S.C. 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay “overlap” under 35 U.S.C. 154(b)(2)(A).

69 Fed. Reg. 34283 (2004). However, the decision in *Wyeth v. Dudas*, 88 U.S.P.Q.2d 1538 (D.D.C. 2008) clearly pointed out the error in the Office’s position. As the court in *Wyeth* has pointed out:

The problem with the PTO’s construction is that it considers the application delayed under §154(b)(1)(B) during the period before it has been delayed. That construction cannot be squared with the language of §154(b)(1)(B), which applies “if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years.” (Emphasis added.) “B delay” begins when the PTO has failed to issue a patent within three years, not before.

Wyeth v. Dudas, 88 U.S.P.Q.2d 1538, 1541 (D.D.C. 2008).

Accordingly, as set forth below, Patentees are entitled to 938 days of patent term adjustment rather than the 526 days indicated on the patent. This is because the 412 day period of adjustment under 37 C.F.R. § 1.702(a) that began on the day after 14 months from the date that the international application satisfied the requirements of 35 U.S.C. § 371 and ended on the day that the first action (restriction requirement) was mailed cannot have overlapped with the 1037 day period under 37 C.F.R. § 1.702(b) that began on the day after the date that is three years after the date that the national phase of the application commenced and ended on the day that applicants filed a request for continued examination.

The sum of the non-overlapping periods under 37 C.F.R. § 1.702 is 1449 days. Subtracting 511 days of applicant delay under 37 C.F.R. § 1.704 results in a final adjustment of 938 days.

The *Wyeth* decision was filed before the patent issued. Accordingly, Patentees submit that the Office was in error in failing to calculate the revised patent adjustment term indicated in the patent in accordance with the decision in *Wyeth*. This issue could not have been raised by the Patentees during the time period set forth in 37 C.F.R. § 1.705(b) because Patentees could not have known that in correcting the error in the calculation

presented in the Notice of Allowance, the PTO would fail to calculate the revised adjustment in accordance with the *Wyeth* decision until the patent issued with the incorrectly revised adjustment indicated thereon.

Furthermore, it is noted that the decision in *Wyeth* has been appealed and that the appeal is pending in the Court of Appeals for the Federal Circuit as case no. 2009-1120. The outcome of that appeal may affect the resolution of this matter. Therefore, to the extent that the patent office did not calculate the revised patent term adjustment in accordance with the *Wyeth* decision because it is the position of the PTO that the issue has not been finally resolved, the Patentees could not have raised the issue during the period set forth in 37 C.F.R. § 1.705(b) because the issue was not yet finally resolved. However, Patentees are mindful that the period set forth in 37 C.F.R. § 1.705(d) is the last available window for filing a request for reconsideration of the patent term adjustment in the PTO. Accordingly, Patentees are filing this request at this time despite the lack of resolution of the appeal. If it is the position of the PTO that patent term adjustment in accordance with the *Wyeth* decision cannot be afforded until the appeal is finally resolved, then Patentees request that consideration of this request be stayed until such time as the appeal is finally resolved.

In accordance with 37 C.F.R. § 1.705(d), this request complies with the requirements of 37 C.F.R. § 1.705(b)(1) & (2) as follows:

- (1) The request is accompanied by the fee set forth in § 1.18(e); and
- (2) Below, Patentees set forth a statement of the facts involved, specifying:
 - (i) The correct patent term adjustment and the basis or bases under § 1.702 for the adjustment;
 - (ii) The relevant dates as specified in §§ 1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in § 1.703(f) to which the patent is entitled;
 - (iii) Whether the patent is subject to a terminal disclaimer and any expiration date specified in the terminal disclaimer; and

(iv)

(A) Any circumstances during the prosecution of the application resulting in the patent that constitute a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in § 1.704; or

(B) That there were no circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in § 1.704.

The Correct Patent Term Adjustment and Bases Under 37 C.F.R. § 1.702.

The correct patent term adjustment is 938 days. The bases under § 1.702 for the adjustment are as follows.

Under 37 C.F.R. § 1.702(a)(1), the issuance of the patent was delayed due to the failure of the Office to mail at least one of a notification under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151 not later than fourteen months after the date on which the application was filed under 35 U.S.C. 111(a). The application was filed on December 6, 2001 and a first action was not mailed until March 24, 2004.

Under 37 C.F.R. § 1.702(b), the patent was delayed due to the failure of the Office to issue a patent within three years after the date on which the application was filed under 35 U.S.C. 111(a), but not including: (1) Any time consumed by continued examination of the application under 35 U.S.C. 132(b). The application was filed December 6, 2001. The date that was three years after the date on which the application was filed was December 6, 2004. A request for continued examination under 35 U.S.C. § 132(b) was filed on October 9, 2007. The patent issued on March 3, 2009.

No time was consumed by an interference proceeding under 35 U.S.C. 135(a), by the imposition of a secrecy order under 35 U.S.C. 181, by review by the Board of Patent Appeals and Interferences or a Federal court, or any delay in the processing of the application by the Office that was requested by the applicant.

The Relevant Dates As Specified In 37 C.F.R. §§ 1.703(a) Through (e)

The relevant dates as specified in §§ 1.703(a) through (e) for which an adjustment is sought are as follows:

In accordance with 37 C.F.R. § 1.703(a), the period of adjustment under § 1.702(a) is the sum of the following periods:

The number of days in the period beginning on the day after the date that is fourteen months after the date on which the application was filed under 35 U.S.C. 111(a) or fulfilled the requirements of 35 U.S.C. 371 and ending on the date of mailing of an action under 35 U.S.C. 132. The application was filed on December 6, 2001. Therefore, the day that is 14 months after day that the application was filed is February 6, 2003. The first action was mailed March 24, 2004. The period beginning on February 7, 2003 and ending March 24, 2004 comprises 412 days.

The period of adjustment under § 1.702(b) is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application and ending on the date a patent was issued, but not including the number of days in the period beginning on the date on which a request for continued examination of the application under 35 U.S.C. 132(b) was filed and ending on the date the patent was issued. The application was filed on December 6, 2001. The day after the date that is three years after the date on which the national stage commenced is December 7, 2004. A request for continued examination under 35 U.S.C. § 132(b) was filed on October 9, 2007. The patent issued on March 3, 2009. Therefore, the period of adjustment under § 1.702(b) beginning December 7, 2004 and ending on March 3, 2009, not counting the period from October 9, 2007 to March 3, 2009, is 1037 days.

Whether The Patent Is Subject To A Terminal Disclaimer

The patent is not subject to a terminal disclaimer.

Circumstances During The Prosecution Of The Application Resulting In The Patent That Constitute A Failure To Engage In Reasonable Efforts To Conclude Processing Or Examination Of Such Application As Set Forth In § 1.704

The circumstances during the prosecution of the application resulting in the patent that constituted a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in § 1.704 were as follows:

On two occasions, applicant is deemed under 37 C.F.R. § 1.704(b) to have failed to engage in reasonable efforts to conclude processing or examination of an application for periods of time in excess of three months that were taken to reply to any notice or action by the Office.

A non-final action was mailed June 20, 2004. The day after the date that is three months after the date of this mailing was September 20, 2004. A reply was filed on December 27, 2004. This period of delay was 88 days.

A non-final action was mailed December 20, 2005. The day after the date that is three months after the date of this mailing was March 21, 2005. A reply was filed June 20, 2006. This period of delay was 92 days.

Applicant is deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application under 37 C.F.R. § 1.704(c) by reason of submission of a reply having an omission (§1.135(c)), in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date the reply having an omission was filed and ending on the date that the reply or other paper correcting the omission was filed.

A reply to a restriction requirement was filed April 29, 2005. The reply was deemed to be non-responsive. A corrected reply was filed May 18, 2005. The period of delay is deemed to be 19 days.

A reply filed May 18, 2005 was deemed to be non-responsive. A corrected reply was filed September 16, 2005. The period of delay is deemed to be 121 days.

Applicant is deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application under 37 C.F.R. § 1.704(c) by reason of submission of a supplemental reply or other paper, other than a supplemental reply or other paper expressly requested by the examiner, after a reply has been filed, in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date the initial reply was filed and ending on the date that the supplemental reply or other such paper was filed.

A reply was filed September 16, 2005, and an IDS was filed September 27, 2005.

The period of delay is deemed to be 11 days.

The cumulative total number of days calculated under 37 C.F.R. § 1.704 is 511 days.

The Adjustment As Specified In 37 C.F.R. § 1.703(f) To Which The Patent Is Entitled

The adjustment as specified in § 1.703(f) to which the patent is entitled is the sum of the periods calculated under paragraphs (a) through (e) of 37 C.F.R. § 1.702, to the extent that such periods are not overlapping, less the sum of the periods calculated under § 1.704. That is, 412 days under 37 C.F.R. § 1.702(a) in the period beginning on February 7, 2003 and ending March 24, 2004, plus 1037 days under § 1.702(b) in the period beginning December 7, 2004 and ending on March 3, 2009, not counting the period from October 9, 2007 to March 3, 2009 — for a sum of 1449 days under 37 C.F.R. § 1.702 less 511 days calculated under 37 C.F.R. § 1.704. That is, the adjustment to which the patent is entitled is 938 days.

CONCLUSION

For the foregoing reasons, the revised patent term adjustment indicated on the patent was in error. The patent term adjustment to which the patent is entitled is 938 days. Reconsideration and correction of the patent term adjustment is respectfully requested.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

Date: May 2, 2009

By: /Christopher L. North/
Christopher L. North
Registration No. 50433

P.O. Box 1404
Alexandria, VA 22313-1404
703 836 6620